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**The National Children's Study: Our Hope for Improving the Health of the Next
Generation of America's Children**

The National Children's Study is a prospective multi-year epidemiological study that will follow 100,000 American children, a nationally representative sample of all children born in the United States, from conception to age 21. The study will assess and evaluate the environmental exposures these children experience in the womb, in their homes, in their schools and in their communities. It will seek associations between environmental exposures and disease in children. The diseases of interest include all those listed above. The principal goal of the Study is to identify the preventable environmental causes of pediatric disease and to translate those findings into preventive action and improved health care.

The National Children's Study was mandated by Congress through the Children's Health Act of 2000. The lead federal agency principally responsible for the Study is the National Institute of Child Health and Human Development. Other participating agencies include the National Institute of Environmental Health Sciences, the Environmental Protection Agency, the Centers for Disease Control and Prevention and the Department of Education. By working with pregnant women and couples, the Study will gather an unprecedented volume of high-quality data on how environmental factors acting either alone, or in combination with genetic factors, affect the health of infants and children. Examining a wide range of environmental factors – from air, water, and dust to what children eat and how often they see a doctor – the Study will help develop prevention strategies and cures for a wide range of childhood diseases. By collecting data nationwide the study can test theories and generate hypotheses that will inform biomedical research and the care of young patients for years to come. Simply put, this seminal effort will provide the foundation for children's healthcare in the 21st Century.

Six aspects of the architecture of the National Children's Study make it a uniquely powerful tool for protecting the health of America's children:

1. The National Children's Study is prospective in its design. The great strength of the prospective study design is that it permits unbiased assessment of children's exposures in real time as they actually occur, months or years before the onset of disease or dysfunction. Most previous studies have been forced to rely on inherently inaccurate retrospective reconstructions of past exposures in children who were already affected with disease. The prospective design obviates the need for recall. It is especially crucial for studies that require assessments of fetal and infant exposures, because these early exposures are typically very transitory and will be missed unless they are captured as they occur.

2. The National Children's Study will employ the very latest tools of molecular epidemiology. Molecular epidemiology is a cutting-edge approach to population studies that incorporates highly specific biological markers of exposure, of individual susceptibility and of the precursor states of disease. Especially when it is embedded in a prospective study, molecular epidemiology is an extremely powerful instrument for assessing interactions between exposures and disease at the level of the individual child.

3. The National Children's Study will incorporate state-of-the-art analyses of gene-environment interactions. Recognition is now widespread that gene-environment interactions are powerful determinants of disease in children. These interactions between the human genome and the environment start early in life, affect the health of our children, and set the stage for adult disorders. The heroic work of decoding the human genome has shown that only about 10-20% of disease in children is purely the result of genetic inheritance. The rest is the consequence of

interplay between environmental exposures and genetically determined variations in individual susceptibility. Moreover, genetic inheritance by itself cannot account for the sharp recent increases that we have seen in incidence of pediatric disease.

4. The National Children's Study will examine a nationally representative sample of American children. Because the 100,000 children to be enrolled in the Study will be statistically representative of all babies born in the United States during the five years of recruitment, findings from the Study can be directly extrapolated to the entire American population. We will not need to contend with enrollment that is skewed by geography, by socioeconomic status, by the occurrence of disease or by other factors that could blunt our ability to assess the links between environment and disease.

5. Environmental analyses in the National Children's Study will be conducted in close collaboration with the Centers for Disease Control and Prevention. The CDC laboratories in Atlanta are the premier laboratories in this nation and the world for environmental analysis. The testing done at CDC is the best available worldwide, making results of environmental analyses unimpeachable.

6. Samples collected in the National Children's Study will be stored securely and will be available for analysis in the future. New tests and new hypotheses will undoubtedly arise in the years ahead. Previously unsuspected connections will be discovered between the environment, the human genome and disease in children. The stored specimens so painstakingly collected in the National Children's Study will be available for these future analyses.

Congress has already laid a firm foundation for the National Children's Study. Between 2000 and 2009, the Congress invested more than \$580 million to design the study and begin building the nationwide network necessary for its implementation. Seven Vanguard Centers and a Coordinating Center were designated in 2005 at sites across the nation – in Pennsylvania, New York, North Carolina, Wisconsin, Minnesota, South Dakota, Utah and California – to test the necessary research guidelines – with plans to expand the program to 41 states and 105 communities nationwide. Findings in these Study Centers have suggested that further refinements are necessary to ensure the most cost-effective investment in implementing the Study and generating policy relevant findings for decades to come. The Study has recently been expanded to thirty additional locations where approaches to recruitment can be more fully optimized. A formative research program will generate new knowledge that will inform redesign of key questionnaires and other data collection approaches, in response to important concerns that were raised by the National Academy of Sciences regarding the original Vanguard protocol.

The tough job of designing and organizing is nearly complete. Funding for the Study this year will permit researchers to begin achieving the results that will make fundamental improvements in the health of America's children. To abandon the Study at this point would mean forgoing all of that dedication, all of that incredible effort, and all of the logistical preparation.

The National Children's Study will yield benefits that far outweigh its cost. It will be an extraordinarily worthwhile investment for our nation, and it can be justified even in a time of fiscal stress such as we face today. Six of the diseases that are the focus of the Study (obesity, injury, asthma, diabetes, autism and schizophrenia) cost America at least \$642 billion each year. If the Study were to produce even a 1% reduction in the cost of these diseases, it would save \$6.4

billion annually, 50 times the average yearly costs of the Study itself. But in actuality, the benefits of the National Children's study will likely be far greater than a mere 1% reduction in the incidence of disease in children. The Framingham Heart Study, upon which the National Children's Study is modeled, is the prototype for longitudinal medical studies and the benefits that it has yielded have been enormous. The Framingham Study was launched in 1948, at a time when rates of heart disease and stroke in American men were skyrocketing, and the causes of those increases were poorly understood. The Framingham Study used path-breaking methods to identify risk factors for heart disease. It identified cigarette smoking, hypertension, diabetes, elevated cholesterol and elevated triglyceride levels as powerful risk factors for cardiovascular disease. These findings contributed powerfully to the 42% reduction in mortality rates from cardiovascular disease that we have achieved in this country over the past 5 decades.

The data from Framingham have saved millions of lives – and billions of dollars in health care costs. The National Children's Study, which will focus on multiple childhood disorders, could be even more valuable. We do not need to wait 21 years for benefits to materialize from the National Children's Study. Valuable information will become available in a few years' time, as soon as the first babies in the Study are born.

Consider, for example, data on premature births. The rate of U.S. premature births in 2003 was 12.3%, far higher than the 7% rate in most western European countries. Hospital costs associated with a premature birth average \$79,000, over 50 times more than the average \$1,500 cost for a term birth. Just a 5% reduction in rates of prematurity would cut hospital costs by \$1.6 billion annually. Within just two years, that savings would match the full cost of the Study.

The Study enjoys a broad group of supporters, including The American Academy of Pediatrics; Easter Seals; the March of Dimes; the National Hispanic Medical Association; the National Association of County and City Health Officials; the National Rural Health Association; the Association of Women's Health, Obstetric and Neonatal Nurses; United Cerebral Palsy; the Spina Bifida Association of America; and the United States Conference of Catholic Bishops, just to name a few. This broad and diverse group recognizes the overwhelming benefits this Study will produce for America's children.

Congress first authorized the National Children's Study in 2000, and has appropriated \$584.8 million since then to design the Study, pursue preparatory research, and designate Study Centers that will be piloting the Study in thirty-seven locations by the end of the calendar year. Products in the form of thoughtful reviews of Study design (including reviews on the hypotheses relating to the epidemic of childhood obesity) have already been published, and are submitted appended to this written testimony for the record. More are already being developed for peer review, and will advance the state of the science of children's environmental health.

Funding for the Study this year requires a commitment of \$194 million. These funds will be used to begin enrolling children in the study. They will enable the NIH to continue establishing the 105 study sites around the country. We urge Congress to fully fund the National Children's Study. It is an investment in our children – and in America's future. The National Children's Study will give our nation the ability to understand the causes of chronic disease that cause so much suffering and death in our children. It will give us the information that we need on the environmental risk factors and the gene-environment interactions that are responsible for rising rates of morbidity and mortality. It will provide a blueprint for the prevention of disease and for

the enhancement of the health in America's children today and in the future. It will be our legacy to the generations yet unborn.